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MONTANA FIRST JUDICIAL DISTRICT COURT,

LEWIS & CLARK COUNTY

THE STATE OF MONTANA, *ex rel* MIKE McGRATH, Attorney General, Plaintiff v. ELI LILLY AND COMPANY, Defendant	Case No.: ADV-2007-188 **COMPLAINT**

The State of Montana (hereinafter "the State"), by and through the Attorney

General of Montana, Mike McGrath, asserts the following claims against Eli Lilly and Company (hereinafter "Defendant" or "Lilly"):

JURISDICTION AND VENUE

1. This is a civil action for damages and civil penalties for violations of the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Anno. § 50-31-101 (2006), the Montana Consumer Protection Act, Mont. Code Anno. § 30-14-101 (2006), the Montana False Claims Act § 17-8-403, *et seq.* (2006), and the other common law causes of action stated herein.

PARTIES

2. This action is brought by the Montana Attorney General in the exercise of his common law and statutory powers.

3. At all times herein mentioned, Defendant Lilly was and is a corporation incorporated, operating, and existing under the laws of incorporation of the State of Indiana, with its principal place of business in Indiana, continuously doing business in the State of Indiana for monetary profit, and also within this judicial district. At all times herein mentioned, Defendant Lilly, in interstate commerce and including this judicial district, purposefully marketed, designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as Zyprexa® (hereafter "Zyprexa" - also known as Olanzapine). According to Lilly's own website, through its Lilly Tippecanoe Laboratories division, Defendant employs over 1,000 associates in Tippecanoe County and manufactures Zyprexa in Tippecanoe County. Upon information and belief, some or all of the Zyprexa ingested by consumers in the State of Montana was

manufactured within Tippecanoe County by Defendant Lilly at its Tippecanoe Laboratories division.

4. According to records maintained with the Indiana Secretary of State, Defendant Lilly may be served with process by and through its registered agent:

Robert A. Armitage
Eli Lilly and Co.
Lilly Corp. Center
Indianapolis, IN 46285

5. At all times herein mentioned, Defendant Lilly was the actor engaged in the acts herein alleged, acting through its agents and employees, and at all times, the actions and omissions asserted in this pleading were committed by agents or employees acting within the purpose and scope of said agency and/or employment, and/or all of said acts and conduct were ratified and approved by said Defendant.

ALLEGATIONS OF FACT

6. At all times relevant, Defendant knew and had reason to know that its drug, Zyprexa, put users at risk for developing severe and harmful health conditions including, but not limited to, hyperglycemia, acute weight gain, diabetes mellitus, exacerbation of diabetes mellitus, pancreatitis, cardiac problems and death. Furthermore, Defendant has been aware of studies linking Zyprexa to these conditions since 1996 and has known since at least 1999 that Olanzapine causes diabetes at a rate far in excess of the risk of most atypical antipsychotics, yet has failed to fully and adequately warn the State, physicians, and consumers of these risks.

7. At all times relevant to this action, Defendant has been responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Zyprexa.

8. In 1996, the United States Food & Drug Administration (hereinafter "FDA") approved Zyprexa for use in the treatment of schizophrenia.

9. In 2000, the FDA approved Zyprexa for use in the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

10. In 2004, the FDA approved Zyprexa for maintenance in the treatment of bipolar disorder, also known as manic-depression.

11. Notwithstanding the limited uses approved by the FDA, Defendant marketed, advertised, and sold Zyprexa for a number of non-approved or "off-label" uses including, but not limited to, Alzheimer Disease, Geriatric Dementia, Tourette's Syndrome, Pervasive Developmental Delay, Autism, Anorexia Nervosa, and general depression. This was in spite of the fact that no testing had demonstrated the safety or effectiveness of Zyprexa for such uses. Lilly recognized that the small number of psychiatric patients would provide an undesirably small market for the product. In a continuing effort to illegitimately receive greater profits from Zyprexa, Lilly's sales force concentrated on primary care physicians, rather than psychiatrists, and focused upon marketing and selling the drug as treatment for depression and anxiety, rather than the psychotic conditions for which Zyprexa had been approved. To this end, Lilly employed its immense marketing resources to encourage and promote sales for unapproved uses. Lilly made this effort even though it knew Zyprexa was not approved for treatment for those conditions.

12. Shortly after Defendant began selling Zyprexa, Lilly began to receive reports of Zyprexa's consumers developing hyperglycemia, acute weight gain, diabetes mellitus, exacerbation of diabetes mellitus, pancreatitis, and other severe diseases and conditions. These conditions occurred not only in patients with the psychiatric

conditions for which Zyprexa had been approved but also in the non-approved or "off-label" uses.

13. Beginning in 1998, scientific journals began to publish studies that established a causal association between using Zyprexa and developing or exacerbating diabetes mellitus (hereinafter "diabetes") and the development of dangerously high blood sugar levels, also known as hyperglycemia. Studies have consistently continued to find a relationship between Zyprexa and these and other dangerous conditions.

14. In April, 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed Zyprexa. The agency reported forty known incidents of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Defendant to warn consumers about the risk of diabetes and diabetic ketoacidosis, and further required Defendant to instruct patients who were using Zyprexa to monitor their blood sugar levels.

15. In that same month, the Japanese Health and Welfare ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis and diabetic coma for users of Zyprexa.

16. Defendant has failed to warn health care providers and consumers in this country, including the State of Montana, about the true nature of the serious risks of diabetes, hyperglycemia, diabetic ketoacidosis, and other serious conditions associated with the use of Zyprexa.

17. The Defendant knew, or was reckless in not knowing, of the risks involved in consuming Zyprexa. Furthermore, the Defendant has been aware of studies and journal articles linking use of Zyprexa with these and other severe and permanent

diseases since 1998. Defendant knew its drug Zyprexa was four times more likely to cause consumers significant weight gain, hyperglycemia, and diabetes than any other atypical anti-psychotic medication, except Clozapine, yet since 2003 has falsely told health care providers and purchasers of Zyprexa that Olanzapine had a "comparable rate" of diabetes with other atypical antipsychotics.

18. Defendant failed to warn consumers, including those in the State of Montana, its physicians and Medicaid recipients, of the dangerous and permanent health consequences caused by the use of Zyprexa. In fact, Defendant instructed its representatives to minimize and misrepresent the dangers of Zyprexa, affirmatively and consciously placing company profits above the public safety. This is particularly true of the prescriptions written for off-label uses. This failure to warn was designed and intended to maximize company profits, even years after Lilly's own experts were internally questioning the safety of Zyprexa.

19. Beginning in 1996, Defendant's strategy has been to aggressively market and sell Zyprexa by willfully misleading potential users about serious dangers resulting from the use of Zyprexa. Defendant undertook an advertising blitz, extolling the virtues of Zyprexa in order to induce widespread use. This marketing campaign consisted of advertisements, telephone conferences, live conferences, direct promotional presentations to doctors and other h ealthcare providers, and other promotional materials provided directly to Zyprexa users. Defendant has also advertised the use of Zyprexa for off-label uses, including geriatric dementia, pediatric symptoms, and for general depression.

20. The advertising program sought to create the impression and belief by consumers and physicians that Zyprexa was safe for human use, and had fewer side effects and adverse reactions than other atypical antipsychotic medications. This was

done even though Defendant either knew these representations to be false or had no reasonable grounds to believe them to be true. By 2002, sales representatives of Lilly were making 460,000 doctor visits per year and minimizing and obfuscating the risk of Zyprexa daily.

21. The advertising program purposefully disguised the risks associated with Zyprexa use, including serious illness and death. Lilly relayed only positive information and relied upon manipulated statistics to suggest widespread acceptability, while at the same time concealing adverse factual material (including, but not limited to relevant information of serious health risks) from the State, physicians, and the general public. In particular, the advertising materials produced by Defendant falsely represented the severity, frequency, and nature of adverse health effects caused by Zyprexa. Further, they falsely represented that adequate testing had been done on Zyprexa. In particular, Defendant misrepresented that testing had been performed for off-label uses when, in fact, no such testing had been done, and the FDA had not approved Zyprexa for such uses.

22. As a result of Defendant's advertising and marketing campaign, Zyprexa has become one of Defendant's top-selling drugs and has been prescribed to over twelve million (12,000,000) people worldwide. In 2003, approximately seven million (7,000,000) prescriptions for Zyprexa were dispensed, resulting in more than two billion dollars ($2,000,000,000) in sales. In 2003, Zyprexa was the seventh largest selling drug in the country. In 2004, Zyprexa sales exceeded four billion, four hundred million dollars ($4,400,000,000).

23. Shortly after Defendant began selling its product Zyprexa, it received reports of Zyprexa's users developing severe and harmful health conditions, including,

but not limited to, hyperglycemia, acute weight gain and associated cardiovascular risks, diabetes, exacerbation of diabetes mellitus, and pancreatitis. These reports further confirmed known risks of Zyprexa. This information was knowingly withheld or misrepresented to consumers in the State of Montana, physicians, and the general public. This information was material and relevant to consumers, physicians and the general public.

24. In making Zyprexa available to all consumers and Medicaid patients, Defendant knowingly misrepresented to consumers in the State of Montana that Zyprexa was as safe and effective as other atypical anti-psychotic medications. The purchase and use of Zyprexa for Montana Medicaid recipients and Montana consumers was based upon such representations by Defendant.

25. The Montana Legislature has charged the Attorney General with the duty to bring appropriate proceedings in court to remedy violations of the Montana FDCA. Mont. Code Ann. § 50-31-505, Montana Consumer Protection Act, Mont. Code Ann. §30-14-101 (2006), and the Montana False Claims Act § 17-8-403, *et seq*. It is the right and duty of the Attorney General, if in his judgment he has adequate cause to believe that unreasonable, extortionate, and excessive charges have been made for public service, by any public service corporation, to institute proceedings whereby rights of state, exercised in behalf of all the people, may be preserved and vindicated.

26. Zyprexa has been prescribed by Montana physicians to many consumers in Montana and particularly to recipients of the Medicaid program of the State of Montana. As a result of ingesting Zyprexa, consumers in Montana and Montana Medicaid patients have suffered serious health effects, which now require further and more extensive medical treatment and health-related care and services. For many of

these individuals, the State is the financially responsible party for these services. The State and its individual citizens and residents have thus suffered and will continue to suffer additional financial loss for the consequential care of those citizens who consumed prescriptions which were ineffective, unsafe, and actively harmful.

27. The Montana FDCA permits the Attorney General to bring an action for fraud perpetrated against the Government. Plaintiff commences this action on behalf of Montana and its citizens to recover treble damages and civil penalties under the Montana False Claims Act § 17-8-403, *et seq*.

28. Because of the atypical antipsychotics' chemically induced sedative effect, also known as somnolence, Lilly has been marketing Zyprexa to physicians for use with geriatric patients, especially those patients diagnosed with dementia and presenting with symptoms of agitation. Somnolence is a known, common side effect of this potent drug class, not an indicated use. Marketing Zyprexa for sedation is a medically improper and unethical chemical restraint.

29. Zyprexa is a highly potent drug laden with numerous serious and even life-threatening side effects primarily indicated to treat schizophrenia and bipolar mania and is not FDA approved to treat the elderly. To the contrary, there have never been any scientifically legitimate studies demonstrating the efficacy or safety of the use of this potent class of drugs in the elderly demographic.

30. Among other things, Lilly created a 280 person sales force to promote Zyprexa exclusively for off-label uses, specifically for Long Term Care ("LTC") facilities to maximize off-label use of Zyprexa sales in elderly population.

31. The purpose and function of the LTC sales force was to market Zyprexa by, *inter alia,* extolling the drug's efficacy for a litany of non-indicated uses to control

elderly patients who presented with agitation, anxiety, insomnia, or otherwise presented with symptoms that required time intensive care through sedation.

32. Lilly's brazen marketing efforts designed to target health care professionals who prescribe drugs to the elderly constitutes off-label marketing strictly prohibited by law.

33. Lilly gave promises of financial benefits, in cash and in kind, to numerous physicians who attended the elderly to cement this unlawful marketing of Zyprexa.

34. Lilly management participated, encouraged, and authorized the unlawful payment of illegal kickbacks to physicians in order to continue generating sales of Zyprexa.

35. Lilly employed a specific sales division devoted to calling upon LTC facilities because of their indigenous population of almost exclusively elderly clientele – one of Lilly's primary target demographics for off-label growth of Zyprexa.

36. Even before Zyprexa had received FDA approval, Lilly was planning a national, aggressive off-label marketing campaign for Zyprexa, as evidenced by its maintenance of an entire sales force devoted to off-label promotion of Zyprexa in the LTC population.

37. Lilly marketed Zyprexa off-label because the drug's on-label uses were far too narrow to achieve the blockbuster revenues Lilly had planned for the drug.

38. Two roadblocks impeded Lilly's planned saturation of the LTC market with Zyprexa. First and foremost, Zyprexa is not approved to treat the elderly for any indication. Second, few elderly patients are diagnosed with schizophrenia or bipolar disorder, the only two indications for which Zyprexa is indicated in any population.

39. Lilly designed a deceptive and misleading marketing campaign to create a

LTC market for Zyprexa. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bipolar disorder; symptoms that Lilly knew were also prolific in the elderly population.

40. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

41. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of symptoms for which Zyprexa was not approved, Lilly violated its obligations under law.

42. Lilly encouraged use of Zyprexa in the elderly to treat any symptoms that might be categorized as relating to dementia. To assist in these efforts, Lilly instructed the sales force to use patient profile detail aids whose focus was on "behavior treatment" such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bipolar disorder, Lilly intended to overcome Zyprexa's lack of any FDA approved market for Zyprexa in the LTC demographic.

43. By directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation, Lilly was propagating the misleading message that Zyprexa was indicated for the treatment of dementia.

44. Lilly's marketing tactics also capitalized on the inherent high stress of health care providers employed in nursing homes and residential care facilities. Such health care providers frequently experience considerable stress to meet the needs and

demands of too many residents. Lilly LTC sales representatives were trained to cater to physicians' frustrations with difficult, time-intensive patients by marketing Zyprexa's efficacy in mitigating the agitation and demands of elderly patients. In truth, this was Lilly's thinly-veiled marketing of Zyprexa as an effective chemical restraint for demanding, vulnerable and needy patients.

45. Lilly organized its Zyprexa sales operations into regional divisions. Lilly's Neuroscience Director, Grady Grant, oversaw the entire LTC division.

46. Mike Murray was a LTC Director for Lilly sales representatives in Florida who was personally involved in implementing and overseeing Lilly's illegal LTC sales practices in that state and also possessed a wealth of first-hand knowledge of Lilly's corporate endorsement of such practices nationwide, including Montana. By March of 2006, however, Murray had become disgruntled with Lilly. Accordingly, Murray met with upper corporate management to discuss a severance from Lilly. At that time, Murray threatened to disclose information about Lilly's off-label marketing scheme and kickback scheme unless he received a beneficial severance.

47. Lilly's concern about Murray's knowledge of Lilly's illegal marketing practices was a subject of discussion amongst Lilly LTC sales representatives during or thereabout the summer of 2006. Lilly arranged for Murray to meet with Lilly's corporate products liability attorney. In July 2006, Murray was offered and accepted a generous severance package in exchange for Murray's execution of a non-disclosure Agreement.

48. Lilly disseminated training materials and required salespersons to attend training seminars during annual National Sales M eetings (held in Atlanta, Georgia), periodic Regional sales meetings (held in South Carolina) and quarterly District sales meetings (held in various states) including Montana.

49. Among other things, Lilly LTC salespersons engaged in role playing exercises that emulated physician sales calls. Since the LTC sales representatives could not discuss Zyprexa's indicated uses in the elderly demographic – because there were none – salespersons were taught to steer conversations with physicians to the discussion of the generic symptoms common in the elderly LTC demographic and to emphasize that Zyprexa was a superior drug to treat "hostility and aggression".

50. Lilly also created fictitious stereotypical patient profiles of agitated, hostile geriatric patients to present to potential referring physicians. Lilly trained its sales representatives to suggest that such hypothetical patients would be medically indicated for treatment with Zyprexa.

51. Lilly also encouraged its LTC representatives to offer financial incentives to physicians to write off-label Zyprexa prescriptions. The payment of and acceptance of the financial incentives in exchange for prescriptions violated the Montana False Claims Act and other applicable laws. One method employed by Lilly to conceal kickback payments under the guise of legitimacy was the creation of a "speaker" program. Lilly even established an annual budget for LTC sales representatives to invest in speaker fees/honoraria as well as an annual entertainment budget to impress and attract physicians' business.

52. For example, Lilly budgeted an extravagant $100,000 annually for a sales representative to spend on speaker fees/honoraria. Lilly also paid "in kind" kickbacks to doctors in connection with these speaking engagements. Lilly paid exorbitant sums for "incidental expenses" for speaking engagements, such as travel, first-rate lodging, extravagant meals and entertainment, all for both physicians and spouses.

53. The following is a summary of tools, methods, and means used by Lilly to

execute its off-label marketing scheme that are pleaded with specificity to this Complaint:

a. Use of LTC sales representatives to call upon LTC facilities, LTC pharmacies, and LTC prescribing physicians to promote a myriad of dangerous off-label uses of Zyprexa for the purpose of inducing Zyprexa to be prescribed to geriatric LTC patients off-label;

b. LTC sales representatives' unsolicited use of non-scientific literature ostensibly "supporting" Zyprexa as safe and effective for the off-label uses being promoted by Lilly's LTC sales representatives;

c. LTC sales representatives' use of scientific literature and deceptive detail aids describing off-label uses of Zyprexa tailored to the LTC setting;

d. Making payments to physicians disguised as fees for "speaking programs" for the sole purpose of inducing physicians to write prescriptions for off-label usage of Zyprexa in the elderly population;

e. Giving lavish gifts to physicians in the form of: chartered fishing trips for physicians and their friends, sporting events, expensive dinners and entertaining, among other things, for the sole purpose of inducing physicians to write prescriptions for off-label prescriptions of Zyprexa in the elderly population;

f. LTC sales representatives' use of confidential private health information to identify LTC physicians in their territories with large volume practices whose use of Zyprexa could be increased as targets for cold call visits to promote Zyprexa off-label;

g. Monitoring LTC sales representatives ability to obtain confidential private health information; and,

h. Monitoring the success of the off-label promotional program and their off-label LTC sales force by carefully monitoring sales revenues of each sales representative and setting high sales goals expected to be met as an ostensible measure of job performance.

54. As a result of, *inter alia,* the unlawful inducements Lilly regularly paid in cash and in kind to physicians and Lilly's unlawful and misleading Zyprexa off-label promotional sales tactics, research now shows that nursing home residents are being fed antipsychotics in record numbers. A study published in the June 13, 2005 *Archives of Internal Medicine* examined the quality of antipsychotic prescriptions in about 2.5

million Medicaid patients in nursing homes and found that "over half (58.2%)," received antipsychotics that exceeded the maximum recommended dosage, received duplicate therapy, or under the guidelines, more than 200,000 nursing home residents received antipsychotic therapy but had "no appropriate indications for use".

55. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat behavioral disorders in elderly patients with dementia is associated with increased mortality.

56. The FDA's examination of the specific causes of these deaths revealed that most were either due to diabetes, heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia). Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect.

57. A "black box" designation is an FDA recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

58. Six months later, on October 18, 2005, the Associated Press reported a study that showed atypicals used to treat elderly patients with dementia-related aggression and delusions can raise their risk of death. The researchers in the study pooled the results of 15 previous studies on atypicals Zyprexa, Risperdal, Seroquel, and Abilify.

59. Among more than 5,000 elderly dementia patients, those taking any of the four drugs faced a 54% increased risk of dying within 12 weeks of starting the drugs, compared to patients taking placebos. According to the AP article, there were 188 deaths among the 3,353 atypical users (over 5.6%) versus 40 in the 1,757 patients receiving a placebo (under 2.3%) and the risks were similar for each atypical.

60. Zyprexa is known to cause a litany of other side effects across all age groups prescribed the drug, including the dramatically increased risk of obesity, diabetes type II, severe metabolic syndrome, hypertension, cardiovascular complications, heart attacks, and stroke. At the same time, Zyprexa and other atypicals continue to cause neurological side effects like the older typical antipsychotics.

61. The State, as the financially responsible party, and in its role as *parens patriae*, has the right to bring this suit for all Zyprexa consumers, including, but not limited to, Medicaid recipients of the State of Montana.

FIRST CLAIM FOR RELIEF
(Strict Products Liability - Failure to Warn)

62. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

63. Defendant is the manufacturer and/or supplier of Zyprexa.

64. The Zyprexa manufactured and/or supplied by Defendant was and is unaccompanied by proper warnings or packaging regarding all possible side effects associated with the use of Zyprexa. The Defendant failed to warn of the comparative severity, incidence, and duration of such adverse effects. The warnings given to the State, physicians, and the general public did not accurately reflect the signs, symptoms, incidents, or severity of the side effects of Zyprexa.

65. Defendant failed to adequately test Zyprexa. Such testing would have shown that Zyprexa possessed serious potential side effects to which full and proper warnings should have been made.

66. The Zyprexa manufactured or supplied by Defendant was defective due to inadequate pre-marketing, post-marketing warnings, packaging, and/or instructions. (After the manufacturer knew or should have known of the risks of injury from Zyprexa, it failed to provide adequate warnings to physicians, the general public, or the State as the prescribers,

users, and financially responsible party, respectively.) Further, Defendant continued to aggressively market Zyprexa for both approved and non-approved uses.

67. Defendant actually knew of the defective nature of Zyprexa, but continued to market and sell Zyprexa without proper warning, so as to maximize sales and profits, and in conscious disregard of the foreseeable harm caused by Zyprexa.

68. As a proximate cause and legal result of Defendant's failure to warn of known dangers associated with the use of Zyprexa, the State and its citizens, corporations, and other business entities have suffered and will continue to suffer damages and is entitled to all the remedies and damages provided by law.

SECOND CLAIM FOR RELIEF
(Strict Products Liability: Design Defect)

69. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

70. At all times material and relevant to this action, Zyprexa was defective in design and manufacture, and was so at the time it was prescribed by doctors participating in the State's Medicaid program. Zyprexa was defective and dangerous in that it caused

serious injuries when used for its intended and foreseeable purpose, i.e., when ingested as prescribed and in the manner recommended by Defendant.

71. The defects in Zyprexa were known to Defendant at the time Defendant began to market and sell Zyprexa. Disclosure by Defendant was inaccurate, incomplete, misleading, and fraudulent. Further, Defendant misrepresented and concealed the fact that Zyprexa was being marketed and used for off-label uses for which it had not been approved and was not known to be effective.

72. Defendant knew Zyprexa would be used by the consumer without inspection for defect and that the State, physicians, and medicinal users of Zyprexa were relying upon

Defendant's representations that the product was safe.

73. Adequate pre-approval and post-approval testing would have revealed the further extent of the dangers of ingesting Zyprexa, and would have shown that the use of Zyprexa could cause extensive medical complications and additional costs for injuries relating to its use.

74. As a proximate and legal result of the design defect, as well as Defendant's failure to adequately test the product so as to discover the defect, the State and its citizens, corporations, and other business entities have suffered and will continue to suffer damages and is entitled to all the remedies and damages provided by law.

THIRD CLAIM FOR RELIEF
(Fraud and Negligent Misrepresentation)

75. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

76. Defendant's warning of side effects associated with Zyprexa contained

false representations and/or failed to accurately represent the material facts of the full range and severity of side effects and adverse reactions associated with the product. Further, Lilly fraudulently misrepresented the appropriateness of the suitability of Zyprexa for unapproved and "off-label" uses.

77. Defendant's claims and assertions to the State of Montana, physicians, and the general public regarding Zyprexa contained false representations as to the safety of Zyprexa and its defective design. Further, Defendant's claims concerning "off-label" use were false and fraudulent. Lilly's fraudulent conduct includes, but is not limited to:

a. Intentionally hiding the findings of clinically significant weight gain from the ingestion of Zyprexa in published literature and from regulatory agencies;

b. Using "research scientists" Richard Borison, M.P. and Bruce Diamond, Ph.D., to perform research who committed unethical and criminal acts during the performance of the underlying research for Zyprexa;

c. Failing to advise the medical community and payors including Montana when core Zyprexa researchers Borison and Diamond pled guilty to multiple court violations of criminal law for racketeering, theft and false statements;

d. Failing to advise the medical community and payors, including Montana, when core Zyprexa researchers Borison and Diamond were placed on the FDA list of Disqualified and Totally Restricted Clinical Researchers. Borison was so listed on November 11, 1998 and Diamond on February 10, 1999;

e. Failing to advise the medical community and payors that core Zyprexa researcher Lois Fabre, M.D., Ph.D. had committed significant irregularities in his research. The FDA served a "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain" on January 19, 2005. Dr. Faber's research clinic was shut down in April of 2005;

f. In paying kickbacks in the form of speaker's fees to physicians who would prescribe large volumes of Zyprexa, much of it for off label uses; and

g. In marketing Zyprexa for uses for which n o legitimate scientific data validated its use.

78. Defendant was negligent in not making accurate representations regarding the side effects and adverse medical conditions caused by the use of Zyprexa.

79. Defendant knew or reasonably should have known through adequate testing that the claims made to the State of Montana with regard to the safety and efficacy of Zyprexa were false or incomplete, and misrepresented the material facts of Zyprexa's unsafe and defective condition.

80. Defendant's misrepresentations in this regard were done with the intention of inducing the State to approve of the distribution of Zyprexa to participants in the Montana Medicaid Program and Montana consumers for both approved and "off-label" uses.

81. As a proximate and legal result of Defendant's fraudulent and/or negligent misrepresentations, the State and its citizens, corporations, and other business entities have suffered and will continue to suffer damages and is entitled to all the remedies and damages provided by law.

FOURTH CLAIM FOR RELIEF
(Negligence)

82. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

83. Defendant had a duty to exercise reasonable care in the manufacture, sale, and/or distribution of Zyprexa, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented side effects. This duty extends to the State of Montana as the party ultimately bearing financial responsibility for Montana Medicaid patients.

84. Defendant breached this duty, as it was negligent in the testing, marketing, manufacture, sale, and packaging of Zyprexa.

85. As a direct and proximate result of Defendant's negligence, the State of

Montana and its citizens, corporations, and other business entities have suffered and will suffer damages and is entitled to all the remedies and damages provided by law.

FIFTH CLAIM FOR RELIEF
(Violations of the Montana Food, Drug and Cosmetic Act: False and Misleading Advertising)

86. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

87. Since 1947, the sale of drugs within Montana has been regulated by the Montana Food, Drug, and Cosmetic Act (Montana FDCA), Mont. Code Ann § 50-31-101, *et. seq.*

88. The Montana FDCA prohibits false or misleading advertising of drugs within the State. Mont. Code Ann. § 50-31,501(1,5). A drug advertisement is "deemed to be false if it is false or misleading in any particular." Mont. Code Ann. § 50-31-107(1). A drug advertisement is also deemed to be misleading if it fails to reveal material facts about the consequences which may result from using the drug in the manner in which the advertisement suggests that it be used. Mont. Code Ann. § 50-31-107(2).

89. In violation of the Montana FDCA, Defendant's advertisements made false and misleading claims to doctors and the public in Montana about the effectiveness of Zyprexa.

90. As a result of Defendant's violation of Montana FDCA, the State and its citizens, corporations, and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

SIXTH CLAIM FOR RELIEF
(Deceit)

91. Plaintiff repeats and realleges the paragraphs above as if set forth fully

herein.

92. In Defendant's advertising and promotional materials, in its marketing tactics in face-to-face meetings with doctors, in its press releases, and in its public advertisements,

Defendant made suggestions of fact that Defendant knew were not true. Such conduct constitutes deceit under Mont. Code Ann. § 27-1-712.

93. Defendant, in its face-to-face meetings with doctors, in its press releases and in public advertisements, suppressed facts about the severe and harmful dangers of Zyprexa, such that, Montana doctors and the public were misled about its dangers. Such conduct constitutes deceit under Mont. Code Ann. § 27-1-712.

94. As a result of Defendant's violation of Mont. Code Ann. § 27-1-712, the State and its citizens, corporations, and other business entities have been damaged and are entitled to all the remedies and damages provided by law.

SEVENTH CLAIM FOR RELIEF
(Unfair Trade Practices and Consumer Protection Act Claim)

95. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

96. Defendant represented that Zyprexa had characteristics, uses, benefits, and/or qualities that it did not have.

97. Defendant represented that Zyprexa was of a particular standard, quality, and grade suitable for consumption when in fact it was not.

98. Defendant advertised Zyprexa with intent not to sell it as advertised.

99. Defendant engaged in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the state of

Montana.

100. Defendant used misrepresentations or omissions of material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa.

101. Defendant's conduct, as described above, constitutes unfair and deceptive practices in violation of Mont. Code Ann. § 30-14-103.

102. As a consequence of Defendant's violation of Mont. Code Ann. § 30-14-103, the State, its citizens, corporations, and business entities have been injured and suffered damages and are, therefore, entitled to all the damages and remedies provided by law.

EIGHTH CLAIM FOR RELIEF
(Unjust Enrichment and Restitution)

103. Plaintiff repeats and realleges the paragraphs above as if set forth fully herein.

104. Lilly engaged in a systematic campaign to over-promote the use of Zyprexa, claiming it was safe and as, or more, effective than traditional, significantly less expensive pharmaceuticals for depression and anxiety.

105. Lilly knew that Zyprexa causes or contributes to hyperglycemia and diabetes and other adverse conditions in users and is no more effective than much cheaper and safer drugs.

106. Lilly had a duty to the State Montana and to the citizens, corporations, and business entities of the State to disclose all material facts about its products and to refrain from over-promoting or falsely promoting its products as safe and more effective than traditional non-steroidal, anti-inflammatory drugs when it knew that was not true.

107. As a result of Lilly's breach of this duty and the misleading suppression of the truth about Zyprexa, Lilly has sold millions of dollars of unnecessary and over-priced Zyprexa to the State of Montana and its citizens, which likely caused adverse cardiovascular effects to the citizens of the State of Montana.

108. Lilly has been unjustly enriched by its false, deceitful, and misleading conduct to the extent that the citizens of the State of Montana and the State of Montana have unknowingly paid excessive costs for Zyprexa when they could have purchased significantly less expensive traditional pharmaceuticals that would have been equally effective and without the severe cardiovascular risks of Zyprexa.

109. As a result of Lilly's conduct, the State of Montana and its citizens, corporations, and other business entities have suffered substantial economic damages and are entitled to damages and all other available remedies.

NINTH CLAIM FOR RELIEF
(Montana False Claims Act, 2006 Mont. Code Title 17-8-403, et seq.)

110. Plaintiffs incorporate by reference and reallege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by the State of Montana under the provisions of the Montana False Claims Act, 2006 Mont. Code Title 17-8-403, *et seq.*

111. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of Montana.

112. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and may continue to cause to be submitted false or fraudulent claims for payment or

approval, directly or indirectly, to officers, employees or agents of the State of Montana, for Zyprexa.

113. At all times relevant to the complaint, Defendant Lilly knowingly violated the Montana False Claims Act.

114. The amounts of the false or fraudulent claims Defendant Lilly caused to be made to the State of Montana were material.

115. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof, paid and may continue to pay for improperly prescribed Zyprexa.

116. At all times relevant to the complaint, Lilly acted with the requisite knowledge.

117. As a direct and proximate consequence of Defendant Lilly's conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

118. The State of Montana would not have suffered these devastating losses had the truth about Defendant's marketing conspiracies been known.

PUNITIVE AND/OR EXEMPLARY DAMAGES

119. Plaintiff realleges and restates all matters alleged above.

120. At all times mentioned herein, Defendant knew of the defective and dangerous conditions of Zyprexa. Defendant knew of its duties and obligations to consumers to provide safe products to them and to warn such consumers of all known dangers and defective conditions. Despite Defendant's knowledge of the dangers and defective conditions inherent in Zyprexa, Defendant callously, recklessly, willfully and wantonly failed to take appropriate steps to remedy the defects in Zyprexa or to warn

users of said dangers, and in fact misrepresented the condition of the drug. The failure of Defendant to remedy defects and to warn consumers was the result of its desires for financial gain.

121. Defendant mass produced, marketed and sold Zyprexa knowing of the dangerous and defective condition. Despite its knowledge of defects, and despite the extremely high risk of injury to users of Zyprexa, Defendant callously, recklessly, willfully and wantonly disregarded the state of knowledge regarding the safety of the drug. The refusal of Defendant to remedy defects was based on its pursuit of financial gain.

122. The aforesaid acts of Defendant constituted actual malice and fraud in that it knew and intentionally disregarded the condition of the Zyprexa which created a high probability of injury to consumers and deliberately proceeded to act in conscious or intentional disregard or indifference to the high probability of injury and misrepresented the condition of the vehicle to the general public.

123. Pursuant to Montana law therefore Plaintiffs are entitled to exemplary and punitive damages in an amount sufficient so that an example will be made of Defendant to promote safety and to provide an incentive for Defendant and others so situated to engage in safer design, testing, production and marketing practices.

PRAYER FOR RELIEF

WHEREFORE, the State of Montana, by and through Attorney General Mike McGrath, prays as follows:

1. That the Court adjudge and decree that Defendant has engaged in the conduct alleged herein.

2. That the Court adjudge and decree that Defendant's advertising and

promotion of Zyprexa was false and misleading in violation of the Montana FDCA.

3. That the Court adjudge and decree that Zyprexa violated Mont. Code Ann. § 27-1-712 and that the State of Montana and its citizens were damaged thereby.

4. That the Court adjudge and decree that such conduct is unlawful and in violation of Mont. Code Ann. § 30-14-103.

5. That the Court, pursuant to Mont. Code Ann. § 30-14-142, assess civil penalties of $10,000.00 against Defendant for each violation of Mont. Code Ann. § 30-14-103 complained of herein and of Mont. Code Ann. § 17-8-403, *et seq*.

6. That the Court, pursuant to Mont. Code Ann. § 30-14-131, enter an order restoring to the State and to the citizens of the State all monies acquired by Eli Lilly and Co. by means of its unlawful practices.

7. That the Court order Defendant to pay restitution which would restore the State of Montana and the citizens of the State of Montana to the financial position that they would have enjoyed absent Defendant's false representa tions and promotion of Zyprexa.

8. That the Court award the State of Montana treble damages pursuant to Mont. Code. Ann. § 17-8-403, *et seq*.

9. That the Court award the State of Montana its attorneys fees and costs.

10. That the Court award the State of Montana punitive and exemplary damages in an amount the Court deems just, necessary, and appropriate.

11. That the Court order such other and further relief as the Court deems just, necessary, and appropriate.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues so triable.

Dated this 6 day of March, 2007.

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